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FOR
ENVIRONMENTAL MANAGEMENT DEPARTMENT
ADMINISTRATIVE PROCEDURES MANUAL

ENVIRONMENTAL MANAGMENT DEPARTMENT ADMINSTRATIVE PROCEDURE MANAUAL

NOT RELATED TO   Approved By:
PLANT SAFETY

Category 1   _____ 4/8/92
EFFECTIVE: May 11, 1992   Director, Environmental Management   Date

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1. **PURPOSE**

   To provide an alternative method to procedures for directing
   Environmental Management Department (EMD) personnel in
   completion of tasks.

2. **SCOPE**

   This procedure prescribes the steps for developing both Single
   Use Instructions and Non-quality Related Instructions for both
   administrative and technical tasks. The contents of this
   procedure are considered guidance for the Non-quality Related
   Instructions (i.e., Desk Instructions). The applicable
   requirements of this procedure are mandatory for quality-
   related Single Use Instructions (SUI).

3. **DEFINITIONS**

   3.1 **Controlled Document Revision Request (CDRR)** - A formal
       request for revision of an instruction, development of an
       instruction, or issuance of a manual (see 3-21000-ADM-
       05.01, Procedure Developement).

   3.2 **Desk Instructions (DI)** - DIs are non-quality related
       instructions prepared at the discretion of the
       Responsible EMD Manager. These instructions are prepared
       to provide assistance to the user rather than to document
       the steps required to achieve compliance with the QA
       requirements or technical requirements. The quality of
       any quality related product produced shall be directly
       verifiable independent of the existence of the DI. DIs
       do not replace required quality related procedures.

   3.3 **History Package** - A file of various drafts of the
       document, any comment review sheets, and any other
       associated documents (as described in 3-21000-ADM-05.05,
       Step 5.8).

   3.4 **E&WM** - Environmental and Waste Management

   3.5 **EMD** - Environmental Management Department

   3.6 **Peer** - See the EMD Document Review Procedure, 3-21000-
       ADM-05.05, Document Review.

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3.7 **QAC** - Quality Assurance Coordinator (QAC) is the Division designee who acts as Division representative in the implementation of the EMD Quality Assurance Program Description.

3.8 **QAPD** - EMD Quality Assurance Program Description

3.9 **QAPM** - EMD Quality Assurance Program Manager

3.10 **Procedure Revision Request (PRR)** - See CDRR and Attchment 1.

3.11 **Responsible Manager** - The responsible manager is the EMD manager responsible for the task being addressed. For Single Use Instructions (SUIs), the Responsible Manager is the Division Manager or QAPM, as applicable. The designee for the preparation of procedures under 3-21000-ADM-05.02, Procedure Development, is assumed to be designee for instructions as well, unless the letter of designation specifies otherwise.

3.12 **Review Executor** - The individual designated by the Responsible Manager to arrange the review of the instruction consistent with Section 5.2 or 5.3.

3.13 **RFP** - Rocky Flats Plant

3.14 **Single Use Instruction (SUI)** - Instructions for quality related tasks that will be completed less than 10 times.

4. **RESPONSIBILITIES**

   4.1 The responsible manager:

   1. Identifies the need for instructions, typically based on staff input.

   2. Arranges for instruction development and review.

   3. Obtains QAPM concurrence with the instruction.

   4. Approves instructions.

   4.2 The instruction author prepares the draft instruction in compliance with this procedure.

4.3   The QAPM reviews all instructions and concurs with valid instructions.

4.4   Designated or required reviewers review the instructions consistent with the requirements of this procedure.

5.   **INSTRUCTIONS**

5.1 **Instruction Development**

5.1.1   Instructions shall be developed or existing instructions revised, as necessary, to control activities within the scope of this procedure.

> **NOTE**
> For DIs, steps 5.1.2 to 5.1.7 may be completed verbally with no written documentation. A unique developmental identifier for the instruction may be assigned to an instruction prior to completion of steps 5.1.2 to 5.1.7. If the instruction is determined to not be required, the copies are destroyed and the number may be reused.

5.1.2   A PRR/CDRR form shall be prepared when individuals identify the need for an instruction or a revision to an instruction. The form shall state the purpose and scope of the proposed instruction or have a draft attached to it.

5.1.3   The PRR/CDRR shall be submitted to the QAPM by the responsible manager.

> **NOTE**
> Steps 5.1.4 and 5.1.5 may be skipped if the Responsible Manager specifies that the suspected duplicate instruction has already been evaluated and found inadequate.

5.1.4   The QAPM shall determine if such an instruction already exists. If such an instruction appears to exist, the QAPM shall note the number of the existing instruction on the PRR/CDRR in the justification section and

return the PRR/CDRR to the Responsible Manager.

5.1.5   If the PRR/CDRR is returned indicating that it already exists and the Responsible Manager determines, after evaluating the existing instruction that a new instruction is still required, the Responsible Manager may return it to the QAPM for processing after initialing and dating the annotation from step 5.1.4.

NOTE
Evaluation of existing instructions to determine if they are adequate for the intended task (see Step 5.1.5) is at the Responsible Manager's discretion. The only documentation of this evaluation required is specified in Step 5.1.5.

5.1.6   The QAPM assigns a unique identifier for the instruction and records this identifier and a unique PRR/CDRR identifier on the PRR/CDRR.

5.1.7   The QAPM sends a copy of the PRR/CDRR to the Responsible Manager and, in the case of an SUI, to the EMD records center, per 3-21000-ADM-17.01, Records Management.

5.1.8   The author shall draft the instruction using the same format illustrated in Attachment 2 of this procedure. Template files of this format are available from your QAC.

NOTE
For DIs the phrase "_NOT QUALITY RELATED_" shall be included in the lower right hand corner of the header. This phrase underlined and in italic is _required_ on all DIs. This area is left blank for SUIs.

5.1.9   SUIs shall specify the preparation of documentary evidence that activities controlled by the instruction have been conducted in compliance with the instruction.

NOTE

Prior to distribution, the author shall obtain a security classification (including Unclassified Nuclear Information) for the instruction, from an authorized classifier.

5.1.10   The review and approval process for:

1.   SUIs is addressed in Section 5.2.

2.   DIs is addressed in Section 5.3.

5.2   SUI Review and Approval

5.2.1   For SUIs the Responsible Manager shall designate a Review Executor.

5.2.2   For SUIs the Review Executor shall invoke the EMD Document Review procedure (3-21000-ADM-05.05) to control a review cycle that solicits comments from:

1.   The QAPM;

2.   At least one peer;

3.   Each affected RFP organization;

4.   Each affected subcontractor, at the discretion of the Responsible Manager;

5.   Others designated by the Responsible Manager (e.g., Site QA, Health and Safety, Traffic).

5.2.3   For SUIs, the QAPM or designee shall review the instruction for compliance with applicable procedures or documents.

5.2.4   Disposition of review comments shall be at the discretion of the Responsible Manager. Reviewer concurrence is required if the reviewer's organization is responsible for the activity/technical area at issue.

5.2.5   The author shall revise the instruction consistent with the resolutions of comments in

the preceding step.

5.2.6   Upon completion of the instruction, the author shall forward a copy of the history package which contains:

o   A copy/original of the completed document review sheets,

o   A copy/original of each draft which was issued for review, and

o   A copy/original of the final revision of the instruction to the QAPM.

5.2.7   The QAPM shall inspect the history package for compliance with this procedure.

5.2.8   If compliant, the QAPM shall sign the instruction on the concurrence line and then submit the instruction to the Responsible Manager for department approval.

5.2.9   The Responsible Manager then approves or disapproves the instruction. In either case, the Responsible Manager returns the package to the QAPM.

5.2.10   The Responsible Manager shall supply a distribution list for this instruction to the QAPM.

5.2.11   The QAPM shall submit the history package to EMD Record Center (per 3-21000-ADM-17.01, Records Management) after making a copy of the approved version of the instruction.

5.2.12   The QAPM shall submit the approved version of the instruction copy and distribution list to document control for distribution per 3-21000-ADM-06.01, Document Control.

5.3   DI Review and Approval

5.3.1   The Responsible Manager designates a Review

Executor for DIs.

5.3.2   The Review Executor arranges a review of the instruction which solicits comments from:

1.   The QAPM;

2.   Each affected RFP organization;

3.   Each affected subcontractor, at the discretion of the Responsible Manager;

4.   Others designated by the Responsible Manager (e.g., Site QA, Health and Safety, Traffic).

5.3.3   The QAPM or designee shall review the instruction to confirm that the task addressed is not quality related. Any content related comments are considered recommendations and do not require resolution.

5.3.4   Resolution and disposition of review comments is at the discretion of the Responsible Manager except as specified in Step 5.3.3. Reviewer concurrence is not required unless the reviewer's organization is responsible for the activity/technical area at issue.

5.3.5   The author revises the instruction consistent with the resolutions of comments in the preceding step.

5.3.6   Upon completion of this process, the author shall forward a copy of the instruction to the QAPM for concurrence.

5.3.7   The QAPM shall sign indicating concurrence if the criteria in step 5.3.3 has been met.

5.3.8   The QAPM shall then send the instruction to the Responsible Manager for approval.

5.3.9   The Responsible Manager may then approve the instruction.

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5.3.10   If the Responsible Manager elects to have the
           DI issued as a controlled document, the
           Responsible Manager shall send a copy of the
           DI and a distribution list to the QAPM for
           controlled distribution.

5.3.11   Upon receipt of the package addressed in Step
           5.3.10, the QAPM shall submit the approved
           version of the instruction copy to document
           control for distribution per 3-21000-ADM-
           06.01, Document Control.

6.   **RECORDS**

The records generated by this procedure are approved SUIs, the
history files for SUIs, and approved DIs issued as controlled
documents.

7.   **REFERENCES**

7.1   EMD Administrative Procedures Manual, 3-21000-ADM-05.05,
      Document Review procedure

7.2   EMD Administrative Procedures Manual, 3-21000-ADM-06.01,
      Document Control procedure

7.3   EMD Administrative Procedures Manual, 3-21000-ADM-17.01,
      Records Management procedure

ATTACHMENT 1

Procedure Revision Notice (PRR)

PRR (Continuation Sheet)

Refer to 1-11000-PAPG-001 or 1-11000-PAPG-002 for instructions.
PRINT or TYPE all information.

Page _____ of _____
PRR No. _____

SAMPLE PROCEDURE REVISION REQUEST (PRR)

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ATTACHMENT 2

Sample Instruction

PREPARATION OF HISTORY FILES	3-21000-MQAI-QA.01 Revision. 0, Draft b PAGE 1 OF 24

ENVIRONMENTAL MANAGMENT QUALITY ASSURANCE INSTRUCTION MANAUAL

NOT RELATED TO   Approved By:
PLANT SAFETY

NOT QUALITY RELATED   _____ _/_/_
EFFECTIVE: _____   Manager, EM Quality Assurance   Date

1.0 PURPOSE/SCOPE

This instruction is intended to describe how document
review history files are prepared for transmittal to
Performance Assurance and/or transmission to the EMD record
center.

2.0 DEFINITIONS/ACRONYMS

2.1 DQA -- Designee of the QAPM
2.2 QAC -- Quality Assurance Coordinator
2.3 QAPM -- Quality Assurance Program Manager
2.4 QAFS -- QAPM Files Secretary
2.5 TER -- Technical Editing Reviewer

3.0 PROCEDURE

RESPONSIBILITY *ACTION*

3.1 QAPM   Designates DQA.

3.2   Transfers document drafts, document
                   reviews, and related information to the
                   DQA.

3.3 DQA   Arranges for maintenance of these future
                   records during the review process (3-21000-
                   ADM-05.05 and any other applicable
                   procedures) in a file system.

3.4   Adds any additional drafts of the document,
                   comment sheets, and other relevant
                   documents to the file system as they are
                   prepared. Items may be removed from the
                   file as necessary to perform required
                   tasks.

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES	3-21000-NQAI-QA.01
	Revision. 0, Draft b
	PAGE 2 OF 24

RESPONSIBILITY   **ACTION**

3.5 DQA   Upon completion of the review and revision
                   process, assembles the history package,
                   consisting of:

                   1. Each draft version of the document
                       subject to review.

                   2. Each comment sheet including
                       documented comment resolution.

                   3. A signed and dated note explaining
                       any missing or mislabeled item, if
                       needed.

                   4. Document version for Performance
                       Assurance based external review,
                       external review outside of RFP, or
                       issuance, as applicable.

                   5. Attachment 1 with all applicable
                       sections of the form completed in
                       the QAC Verification Section and
                       the header information except the
                       signatures and the dating of
                       signatures.

                   6. EMD Records Transmittal form with
                       all items addressed in package
                       listed except for Attachment 1.
                       Attachment 1 is an internal
                       tracking form and not a QA record.

3.6   Verifies package adequacy.

3.7   Signs and dates Attachment 1 preparation
                   line.

3.8   Delivers the package to the TER.

3.9 TER   Verifies that the items listed in EMD
                   Records Transmittal form (see Step 3.5 item
                   6) and Attachment 1 (see Step 3.5 item 5)
                   are included in the package.

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES	3-21000-NQAI-QA.01
	Revision. 0, Draft b
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RESPONSIBILITY	*ACTION*
3.10	If Step 3.9 is unsatisfactory, contacts the QAC to resolve discrepancy.
3.11 QAC	Resolves any discrepancies noted in Step 3.9.
3.12 TER	Verifies that the Header in Step 3.5 item 5 is consistent with applicable requirements. If requirements are unclear, contacts the DQA for assistance.
3.13 TER	Verifies that each comment resolution indicated on the document review sheets are incorporated in the draft document as addressed in Step 3.5 item 2. If incorporation is unclear, contacts the QAC for assistance in clarifying.
3.14	Upon completion of verification of each set of document review sheets, documents this verification by recording commenter's name, review sheet set date, and initialing on Attachment 1. This may be done after Step 3.17.
3.15	If Steps 3.9 to 3.12 were unsatisfactory, contacts the QAC to resolve discrepancy.
3.16 QAC	Resolves any discrepancies noted in Steps 3.9 to 3.13.
3.17 TER	Documents any outstanding concerns in the comment section.
3.18	Upon completion of Steps 3.9 to 3.17, signs and dates the verification section of Attachment 1.
3.19	Returns package to QAC.
3.20 QAC	Prepares any required transmittal memo(s).
3.21 QAPM	Reviews transmittal memo(s).

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ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES   3-21000-MQAI-QA.01
                                                      Revision. 0, Draft b
                                                              PAGE 4 OF 24

RESPONSIBILITY *ACTION*

3.22 QAC   Resolves memo(s) contents with the QAPM
                (see Step 3.21).

3.23   Prepares final transmittal memo(s).

3.24   Provides memo(s) and package (from Step
                3.19) to QAPM for approval.

3.25 QAPM   Approves transmittal memo(s) by signing
                them as appropriate or returns memo(s) and
                package to the QAC for revision per QAPM
                direction.

3.26 QAC   Removes Attachment 1 from the package for
                inclusion with the SAIC file copy of the
                transmittal package only.

3.27   Arranges for transmission of the package,
                then completes the transmission section of
                Attachment 1.

3.28   Delivers Attachment 1 to the QAPM files
                secretary.

3.29 QAFS   Files Attachment 1 with the SAIC file copy
                of the package (see Step 3.26).

4.0   **REFERENCES**

      3-2100-ADM, 05.05, Document Review

5.0   **ATTACHMENTS**

      Attachment 1: History File Verification Form

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ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES   3-21000-MQAI-QA.01
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ATTACHMENT 1
HISTORY FILE VERIFICATION FORM

QAC _____   Phone _____   Page 1 of __

Document
Title:_____

Document No._____ Revision____ Current Draft_____

QAC VERIFICATION SECTION

Package Contents (number of items):

Drafts (not including final) ____   Final Draft _1_
Comment Sheet Packages ____   Other items ____
Pages of EMD Document Transmittal Form ____

QAC Signature _____   Date _____

TER VERIFICATION SECTION

Header Verified
  Format: Yes __ No __   Organization Name: Yes __ No __

Comment Inclusion Verified:
  Commenter   Sheet   Verified
                                     Date   (initial)

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ATTACHMENT 2 (Continue)

Sample Instruction

ATTACHMENT 1 (Continued)
HISTORY FILE VERIFICATION FORM (Continued)

Document No._____ Revision____ Current Draft_____

TER VERIFICATION SECTION (Continued)
Comment Section:

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TER Name_____ Signature_____ Date____

QAC TRANSMISSION SECTION
Transmitted:

QAC Signature_____   Date____

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